



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Confirmation No.: 5055

Examiner: S. Priebe, Ph.D.

Group Art Unit: 1633

Attorney Docket No.: 2578-3833.9US

NOTICE OF EXPRESS MAILING

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of any cited foreign patents, publications, or pending unpublished U.S. applications are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement is not required to be provided if it was previously cited by or submitted to the office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified above, and is relied upon for an earlier filing date. The references are as follows:

Other Documents

#Submissions of Patentee to the European opposition proceedings, received at the EPO on Sep 25, 2006, including one cited document: ZAVIZION et al., Transformation of Human Corneal Endothelial Cells by Microinjection of Oncogenes, 1990, Bull Exp Biol Med, pp. 519-22, Vol. 109, Plenum Publishing corporation (listed separately below).

#ZAVIZION et al., Transformation of Human Corneal Endothelial Cells by Microinjection of Oncogenes, 1990, Bull Exp Biol Med, pp. 519-22, Vol. 109, Plenum Publishing corporation.

#Submissions of Opponent Serono International to the European opposition proceedings, received at the EPO on Sep 22, 2006.

#ULFENDAHL et al., A novel adenovirus-2 E1A mRNA encoding a protein with transcription activation properties, The EMBO Journal, 1987, pp. 2037-44, Vol. 6, No. 7, IRL Press Limited, Oxford, England.

#Declaration of Amine Kamen, including six exhibits: (1) Conference schedule of sixth conference on Protein Expression in Animal Cells (6th PEACe) held in Mont-Tremblant, Canada, September 7-11, 2003; (2) Abstract of Presentation of Dr. van der Eb entitled "Isolation of adenovirus E1-transformed human cell lines; PER.C6TM as a platform for production of proteins; (3) SHAW et al., Preferential transformation of human neuronal cells by human adenoviruses and the origin of HEK 293 cells, FASEB Journal, pp. 869-87, Vol. 16 (listed below separately); (4) BYRD et al., Malignant transformation of human embryo retinoblasts by cloned adenovirus 12 DNA, Nature, 1 July 1982, pp. 69-71, Vol. 298 (listed below separately); (5) SCHIEDNER et al., Efficient Transformation of Primary Human Amniocytes by E1 Functions of Ad5: Generation of New Cell Lines for Adenoviral Vector Production, Human Gene Ther., 2000, pp. 2105-16, Vol. 11 (listed below separately).

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#BYRD et al., Malignant transformation of human embryo retinoblasts by cloned adenovirus 12 DNA, Nature, 1 July 1982, pp. 69-71, Vol. 298.

#SCHIEDNER et al., Efficient Transformation of Primary Human Amniocytes by E1 Functions of Ad5: Generation of New Cell Lines for Adenoviral Vector Production, Human Gene Ther., 2000, pp. 2105-16, Vol. 11.

#Cell line: 293, Cell type: human embryonal kidney, copyright 2004 DSMZ GmbH, <http://www.dsmz.de/human_and_animal_cell_lines/info.php?dsmz_nr_305&term=293&highlight>.

#PER.C6TM Cell Line (Crucell), printout of the third slide of the www.niaid.nih.gov/hivvaccines/pdf/Ledwith.pdf <<http://www.niaid.nih.gov/hivvaccines/pdf/Ledwith.pdf>>.

#MATSUI et al., Adenovirus 2 Peptide IX Gene Is Expressed Only on Replicated DNA Molecules, Molecular and Cellular Biology, Dec. 1986, pp. 4149-54, Vol. 6, No. 12.

#RICE et al., Multiple Effects on the 72-kDa, Adenovirus-Specified DNA Binding Protein on the Efficiency of Cellular Transformation, Virology, 1987, pp. 366-76, Vol. 156.

#Submissions of Opponent Cevc to the European opposition proceedings, received at the EPO on Sep 22, 2006.

#From Japanese prosecution: MAAT et al., The Nucleotide sequence of adenovirus type 5 early region E1: the region between map positions 8.0 (hindIII site) and 11.8 (SmaI site), Gene, 1980, pp. 27-38, Vol. 10.

#Submissions of Patentee to the European opposition proceedings, transmitted to the EPO on October 12, 2006 including three cited documents listed separately below.

#CARAVOKYRI et al., Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5, Journal of Virology, Nov. 1995, pp. 6627-6633, Vol. 69, No. 11.

#KROUGLIAK et al., Development of Cell Lines Capable of Complementing E1, E4 and Protein IX Defective Adenovirus Type 5 Mutants, Human Gene Therapy, December 1995, pp. 1575-1586, Vol. 6.

Serial No.: 10/618,526

#HEHIR et al., Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications to Prevent their Occurrence, Journal of Virology, Dec. 1996, pp. 8459-67, Vol. 70, No. 12.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/219,414

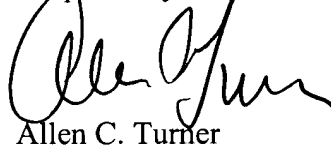
Filed: August 15, 2002

For: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

Respectfully submitted,



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Date: October 4, 2006

ACT/bv

Enclosures: Form PTO/SB/08

Cited Non-U.S. Patent Documents

Document in ProLaw



PTO/SB/08B(10-03)

Approved for use through 7/31/2006. OMB 0651-0031

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/618,526
Filing Date	July 11, 2003
First Named Inventor	Fallaux et al.
Group Art Unit	1633
Examiner Name	S. Priebe, Ph.D.
Attorney Docket Number	2578-3833.91JS

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#Submissions of Patentee to the European opposition proceedings, received at the EPO on Sep 25, 2006, including one cited document: ZAVIZION et al., Transformation of Human Corneal Endothelial Cells by Microinjection of Oncogenes, 1990, Bull Exp Biol Med, pp. 519-22, Vol. 109, Plenum Publishing corporation (listed separately below).	
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		#ULFENDAHL et al., A novel adenovirus-2 E1A mRNA encoding a protein with transcription activation properties, The EMBO Journal, 1987, pp. 2037-44, Vol. 6, No. 7, IRL Press Limited, Oxford, England.	
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		#Cell line: 293, Cell type: human embryonal kidney, copyright 2004 DSMZ GmbH, < http://www.dsmz.de/human)and)animal_cell_lines/info.php?dsnz_nr_305&term=293&highlight >.	
		#PER.C6™ Cell Line (Crucell), printout of the third slide of the www.niaid.nih.gov/hivvaccines/pdf/Ledwith.pdf < http://www.niaid.nih.gov/hivvaccines/pdf/Ledwith.pdf >.	

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Serial No.: 10/618,526

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/618,526
		Filing Date	July 11, 2003
		First Named Inventor	Fallaux et al.
		Group Art Unit	1633
		Examiner Name	S. Priebe, Ph.D.
Sheet 2 of 2	Attorney Docket Number	2578-3833 9LIS	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#MATSUI et al., Adenovirus 2 Peptide IX Gene Is Expressed Only on Replicated DNA Molecules, Molecular and Cellular Biology, Dec. 1986, pp. 4149-54, Vol. 6, No. 12.	
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Examiner Signature		Date Considered	
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